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THE PESTICIDE DATA PROGRAM

**Designed For Risk
Assessment Evaluations**

*U.S. DEPARTMENT OF AGRICULTURE
Agricultural Marketing Service
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**United States
Department of
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National Agricultural Library

THE PESTICIDE DATA PROGRAM (PDP)

Designed For Risk Assessment Evaluations

"What is being done to ensure the safety of our food supply?"

The issue of food safety has rapidly gained attention from the U.S. media in recent years. There is currently a high level of interest in the use of pesticides and, especially, the residues that remain in the nation's food supply. The American public deserves an answer to this very important question.

What Should We Do?

In recent years the American public has been advised to alter their dietary habits to increase their consumption of fresh fruits and vegetables. These foods have been depicted as "healthy foods," and concern about their contamination with pesticides is increasing.

Although most people do not object to the use of pesticides for control of disease carrying insects, pesticide use on food usually elicits strong objections from the American consumer. Public distrust of pesticides is being fueled by recent news media reports, which underline the Federal government's lack of adequate information to assess potential health risks associated with pesticide residues in food.

Having recognized the increasing need for high quality data on chemical residues in food, the U.S. Department of Agriculture (USDA) developed and implemented the Pesticide Data Program (PDP) in May of 1991. The goal of PDP is to provide objective, comprehensive data on pesticide residues in fresh fruits and vegetables, as close to the consumer level as possible. All data produced by PDP will be available for use by the Environmental Protection Agency (EPA) to conduct dietary risk assessments, address pesticide reregistration issues, and complete the special review of troublesome pesticides.

PDP's data gathering activities are not influenced by the agricultural industry or interest groups. PDP data are totally objective in nature, and are presented without any interpretations or recommendations.

Coordination of USDA, EPA, and FDA:

Four USDA Agencies, the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA), signed a Memorandum of Understanding (MOU) to coordinate planning and procedural efforts for PDP. The four USDA Agencies participating in PDP are: the Agricultural Marketing Service (AMS), the Economic Research Service (ERS), the Human Nutrition Information Service (HNIS), and the National Agricultural Statistics Service (NASS). As stipulated by the MOU, USDA has established an Executive Steering Committee for long range planning and communication needs.

The USDA's role is to develop a statistically defensible sampling plan based on food consumption surveys and to manage the day-to-day operations of the program. USDA's AMS has been charged with implementation and management of PDP. AMS also serves as liaison with the nine participating State Departments of Agriculture, the California Department of Pesticide Regulations, and two regional USDA laboratories.

USDA has maintained its commitment to evaluate data collection needs with EPA and FDA officials as frequently as warranted. AMS continuously works with EPA to develop program plans, and to prioritize the inclusion of commodities and pesticides in PDP based on EPA's needs.

Day-to-day operations are managed through frequent communication between AMS and the participating States and regional laboratories. AMS holds periodic PDP meetings with all agencies and parties concerned to discuss future program development, sampling and analytical testing procedures, and data management requirements. These meetings provide an excellent opportunity for open communication and networking.

EPA makes most residue testing decisions, and also provides USDA with a list of registered pesticides for data collection. Program operations are designed so that changes requested by EPA can be easily implemented. AMS maintains contact with several offices at EPA including the Office of Pesticide Programs, and the Office of Policy, Planning, and Evaluation. PDP data will not only be used by EPA for dietary risk assessment, but may also be used to corroborate or refute findings presented by pesticide registrants.

FDA provides USDA with commodity coding systems, residue data-recording information, and commodity preparation information. The PDP database is compatible with FDA's nomenclature system which enhances uniform data reporting among government agencies. In addition, information collected by the program is assisting FDA by pinpointing areas where closer surveillance may be required and by providing information on the use of post-harvest fungicides.

How Does PDP Operate?

PDP sampling and testing operations are conducted by the participating States. Thus, approximately 86 percent of PDP's budget is sent to the States to cover their operational costs. An additional five percent covers contractual services provided by other Federal agencies.

Unlike other State and Federal programs whose purpose is to ensure compliance with current regulations, PDP's objective is to evaluate whether there is a need to revise these regulations. To accomplish this objective, PDP was designed to detect pesticides at very low concentrations; therefore, ensuring that if any targeted pesticides are present, they will be detected. This will provide a significant increase in available data for risk assessments. This is possible because laboratories participating in the program have been equipped with state-of-the-art technology. The capability of PDP participating laboratories to detect low levels of pesticide residues is constantly improving and, as a result, the number of samples with detected residues has increased from 22 percent at the onset of the program to over 50 percent at present.

Currently, manufacturers are not required to analyze the effects of multiple pesticide residues, although existing regulations allow for the application of many different pesticides to a single crop. Therefore, a consumer may be exposed to a combination of different pesticide residues in a single serving of fruits or vegetables. Prior to PDP, there were no data available to assess the effects of exposure to multiple residues. PDP data show the presence of multiple pesticide residues, and, in some cases, as many as nine different residues have been detected in one sample. This information will be available to EPA to evaluate the need for revision of existing regulations.

State Participation:

To expedite program implementation and reduce costs, PDP developed Cooperative Agreements with the respective State agencies, which allowed for sample collection and analyses utilizing existing State sampling operations and laboratory facilities. There are currently nine participating States which, combined, represent approximately 50 percent of the Nation's population. They are as follows:

California	Michigan	Ohio
Colorado	New York	Texas
Florida	North Carolina	Washington

The participating States benefit from the program in many ways such as:

- Approximately 86 percent of PDP's funds are distributed to the participating States to cover program operations. Since PDP enhances a State's regulatory food safety operation, it helps reduce the amount of State funding required for this purpose; thereby, allowing each State to redirect funding to other State programs.

- PDP has purchased state-of-the-art equipment and provided training for all participating State laboratories.
- PDP funds allocated to the States allow for hiring additional laboratory personnel.
- Networking between participating States provides an excellent opportunity to share technical knowledge and problem solving techniques. States use the experience gained through PDP to enhance their own regulatory programs.

Sampling sites located in three of the participating States also distribute a significant amount of produce to other States. For example, approximately 50 percent of Hawaii's and 75 percent of Nevada's produce comes from California, 60 percent of New Jersey's produce comes from New York, and Washington supplies approximately 95 percent of Alaska's produce. Therefore, although Hawaii, Nevada, New Jersey, and Alaska are not PDP participating States, PDP data will apply to their population as well. Ten to 20 percent of the produce distributed to Arizona, Connecticut, Massachusetts, New Mexico, Oklahoma, Oregon, Vermont, and Wyoming is routed through one or more of the PDP participating States.

Data Management:

AMS has worked with both a data management contractor and the AMS Information Resources Management Division (IRMD) to develop and implement the PDP information management system. Appropriate personnel from EPA, FDA, and other USDA agencies were interviewed throughout the development phase to incorporate their requirements.

All PDP data are maintained in the database located at the AMS Residue Branch. This database will definitely be one of the more advanced databases with regard to uses, compatibility, and electronic access. There will be a minimum of two years worth of data on-line at all times, and archived data will be easily accessible through the use of magnetic tape. All data will be made available to EPA and FDA on request.

Standard Operating Procedures:

Program operations for sample collection, analysis, and financial management are required to adhere to PDP Standard Operating Procedures (SOPs). The SOPs for sample collection and analysis are based on EPA's Good Laboratory Practice (GLP) standards. Financial management SOPs follow the applicable Federal regulations.

Adherence to the SOPs provides uniformity of procedures among the participating States and laboratories. This will ensure that analytical results originating from different laboratories may be combined and used to make inferences for the Nation as a whole.

Quality Assurance:

Quality assurance reviews are performed both internally by the participating States and by USDA personnel. These serve the purpose of not only verifying standardization among facilities, but also as a means to transfer important ideas, comments, and recommendations. Quarterly reviews of the laboratory and sampling procedures are conducted by the States. In addition, annual reviews are performed by USDA/AMS.

PDP requires that all residues found be confirmed by an alternate method of detection. The confirmatory analysis provides an extra measure of confidence in both the identification of the pesticide residue and its concentration. Additionally, if the detected residue is in violation of the regulations, the laboratory is required to repeat the testing procedure from the very beginning. If the repeat analysis confirms the initial violation, the appropriate State agencies, FDA, and the AMS Residue Branch are notified.

All participating laboratories are required to take part in the PDP Proficiency Check Sample Program to evaluate their performance. Each quarter, three to four commodities containing several pesticides of known quantities are sent to the participating laboratories. The check samples are tested under the same conditions as their routine samples and the results are submitted to the Residue Branch. Once the results have been received and evaluated, a Proficiency Check Sample Report is written and given to the States to provide information on their performance. Thus, the proficiency check samples serve as a valuable learning tool.

Program Commodities:

National consumption data were used to determine which commodities should be included in the program. To account for seasonal variability, PDP policy mandates that once a commodity is in the program it must continue to be sampled for a minimum of two years. Once the cycle is complete, EPA can request the sampling and analysis of different commodities. The following twelve commodities, which are some of the most widely consumed by the American public, are currently sampled by PDP:

Apples	Celery	Lettuce
Bananas	Grapefruit	Oranges
Broccoli	Grapes	Peaches
Carrots	Green Beans	Potatoes

Sampling Procedures:

PDP has implemented a statistically defensible sampling plan whereby the probability of site selection is based on the amount of produce distributed by the site. This plan was developed with the statistical support of the USDA National Agricultural Statistics Service (NASS), who will provide long-term maintenance and support for the sampling system.

Information obtained through PDP sampling provides data which can be used to make national inferences based on the States sampled. As previously stated, PDP's nine participating States represent 50 percent of the Nation's population, and are suppliers of produce to several additional States.

Samples are collected at sites such as terminal markets and large distribution centers, which allows for sampling as close to the consumer level as possible. Sampling at these locations provides grower and packer information, and takes into account pesticide degradation that has occurred during transit and storage.

The PDP sampling plan includes several other factors which must be considered for valid risk assessments, such as: (1) the number of samples collected each month is proportional to State population, (2) sampling dates are selected at random, and (3) there is no predetermination on product variety or origin.

All participating States are required to follow the PDP Standard Operating Procedures for Sampling, which are based on EPA's Good Laboratory Practices.

Laboratory Procedures:

Of the more than 7,800 PDP samples analyzed to date, approximately 50 percent have been found to contain pesticide residues. This high rate of residue detections is due to the ultra high sensitivities of the instrumentation used and the expertise developed by the technical staff.

Samples are prepared emulating the practices of the average consumer. For example, the bananas and citrus fruits are peeled; peach pits, apple cores, and any other inedible portions are discarded.

Most of the pesticides in the program are tested by multiresidue methods which allow for the detection of 34 pesticides of interest to EPA and many additional compounds. Some, however, require "specialty methods" that are designed to detect specific compounds only. PDP has engaged the services of two USDA regional laboratories to perform these tests.

Laboratory facilities must follow the PDP Standard Operating Procedures for Laboratory Operations; however, they are given flexibility to fine tune their operations, taking into account individual working conditions, personnel, etc.

Where Do We Go From Here?

Throughout 1991 and 1992, PDP has provided some of the most comprehensive data ever obtained on pesticide residues in fresh fruits and vegetables. This approach has been acceptable to, and has received the full support of, EPA.

Other commodities of interest to EPA will be added in the future to replace those that have been in the program since its beginning in 1991, and may include selected processed products. In addition, steps are being taken to include other pesticides of interest to EPA.

California will implement a special survey program whereby 1,200 samples will be collected at over 1,000 public markets, which operate seasonally in selected counties.

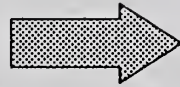
By early 1994, PDP will implement a system to electronically transfer the analytical results from the various participating laboratory facilities directly to the Residue Branch.

THE PESTICIDE DATA PROGRAM

Risk Assessment

- National Inferences
- Reregistration and Special Review of Pesticides

Management and Operations

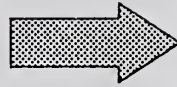


Interagency Coordination

- Memorandum of Understanding (USDA, EPA, FDA)
- Executive Steering Committee
- Long Range Planning
- Semi-Annual Plans

Federal and State Cooperation

- Cooperative Agreements with States:
*California, Colorado, Florida, Michigan,
New York, North Carolina, Ohio, Texas, Washington*
- Allocation of Funding



Sampling

- Statistically Defensible
Proportional to Site Volume
Proportional to State Population
- Near Consumer Level
- Standard Operating Procedures
- Retains Origin of Product

Laboratory Analysis

- Targeted Pesticide List
- Standard Operating Procedures
- Quality Assurance System
EPA GLPs
Proficiency Check Sample Program
- Residue Verification

Data Management

- Oracle Based System
- Electronic Transfer of Data
- Profile Search and Data Collation



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